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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,859	05/25/2001	Mary E. Gerritsen	09800080-0035	9530

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EXAMINER	
QAZI, SABIHA NAIM	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,859	GERRITSEN ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *5,7,15,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Non-Final Office Action

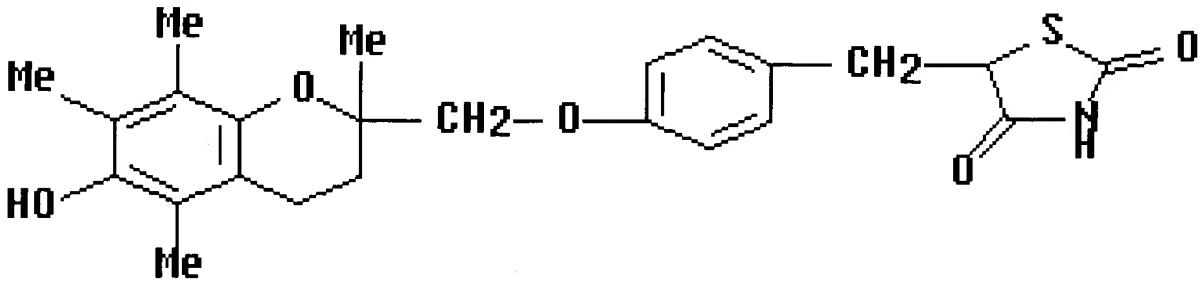
Acknowledgment is made of the Brief filed on May 20, 2004. Finality of the previous Office Action is withdrawn.

The 102-inherency rejection over URBAN et al (US Patent 5,814,647) in the first Office Action is retained. The rejection under 103 is *completely* withdrawn. A new 112-scope rejection has been added. A complete Office Action is as follows.

Claims 1-18 are pending. No claim is allowed.

Claims 5, 7, 15, 17, and 18 are drawn to non-elected invention. The elected invention is Group I, which is drawn to the compounds of Formula I. Therefore claims 5, 7, 15, 17, and 18 are withdrawn from consideration as non-elected invention.

The elected species is:



which is a benzopyran –2,4-thiazolidine dione derivative, namely (+)-5-((4-(3,4-dihydro-6-hydroxy-2,5,7,8-tetramethyl-2H-1-benzopyran-2-yl)methoxy)phenyl)methyl)-2,4-thiazolidione, also known as troglitazone.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims 1-4, 6, 8, 9, 11, 13, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by URBAN et al (US Patent 5,814,647). See the abstract; lines 48-67, col. 1; lines 1-34, col. 2. ; examples 5, 6 and 8. Troglitazone is disclosed as a ligand for the orphan nuclear receptor PPAR Gamma. Translocation of this transcription factor in the nucleus of cells at sufficient rates inhibits transcription and reduces progesterone production in normal granulose cells without a loss of cell viability. However, this inhibition of transcription in rapidly dividing cancer cells expressing PPAR gamma results in the loss of cell viability and inhibition of cell growth.

Troglitazone and related compounds are disclosed for use in the treatment of cancer, to impair the growth of cancer cells without killing normal cells. See lines 40-43, col. 3. Method of inhibiting angiogenesis is not recognized by the prior art however; it discloses the use of troglitazone for treatment of tumor cells and cancer. See also examples 5, 6 and 8. All the elements are taught by the prior art.

See Exparte Novitski, 26 USPQ 2d 1389 (January 22, 1993) which is decision of USPTO Board of Appeals, holding to be inherent and not patentable, inoculating healthy plants with a

known plant inoculant's, employed in the prior art to protect them against phytopathogenic fungi. Novitski discovered that the known plant inoculants would also protect them against root dwelling plant pathogenic nematodes, a discovery neither known nor appreciated by the prior art. The step of inoculating plants with the same inoculants necessarily and inherently protects them against nematodes.

See Atlas Powder versus Ireco, 51 USPQ 2d 1943, (Fed. Cir. 1999), holds the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition does not render the old composition new to the discoverer.

The fact that prior art taught away from the claim is, in fact, only a showing that prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency.

As is clear from the above discussion and citations that the instant invention is a known process of inhibition of tumor by troglitazone therefore is inherently taught by the prior art of record and other thiazolidine compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 10 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of inhibiting angiogenesis for treating certain cancer, does not reasonably provide enablement for the disease or disorder selected from the group consisting of a neoplasm, rheumatoid arthritis, psoriasis, atherosclerosis, diabetes, endometriosis, obesity, thyroid hyperplasia, endometriosis, lung and chronic inflammations, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In the Specification, there is nothing to support the treatment of diseases or disorders selected from the group consisting of a neoplasm, rheumatoid arthritis, psoriasis, atherosclerosis, diabetes, endometriosis, obesity, thyroid hyperplasia, endometriosis, lung and chronic inflammations, etc. by inhibiting PPAR gamma ligands, where the angiogenesis is inhibited in the patient.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ

150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention: The claims are drawn to a method of inhibiting angiogenesis by administering to a patient a therapeutically effective amount of a PPAR gamma ligand.

(2) The predictability or unpredictability of the art: There is lack of predictability in the in the pharmaceutical art.

(3) The breadth of the claims: The claims are broad; they include ***ANY*** PPAR gamma ligand.

(4) The amount of direction or guidance presented: There is no guidance in the disclosure on how to use the invention successfully for the treatments of such a wide variety of diseases.

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971).

(5) The presence or absence of working examples: There are no working examples and/or data *in vivo* or *vitro* to support the claimed invention. The disclosure does not contain any working examples. There are some assays and some techniques in the specification, but they are not useful in the treatment of the said diseases or disorders as claimed.

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(6) The quantity of experimentation necessary: Since there are no working examples, no data, and no guidance presented in the disclosure, one skilled in the art at the time of invention would have to go through undue experimentation to make and use the presently claimed invention.

In the Specification, there is no support for the treatment of diseases or disorders selected from the group consisting of a neoplasm, rheumatoid arthritis, psoriasis, atherosclerosis, diabetes, endometriosis, obesity, thyroid hyperplasia, endometriosis, lung and chronic inflammations, etc. by inhibiting PPAR gamma ligands, where the angiogenesis is inhibited in the patient. ***There is nothing to show that these diseases or disorders can be treated successfully by inhibiting a PPAR gamma ligand, where the angiogenesis is inhibited in the patient.***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Qazi

SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sunday, September 19, 2004